SEP 1 1 2002

Attachment I

K021946

510(K) Summary
Cell Robotics Ultra-Light Laser System

This 510(K) Summary of safety and effectiveness for the Cell Robotics Ultra-Light Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cell Robotics, Inc.
Address:	2715 Broadbent Parkway NE Albuquerque, NM 87107
Contact Person:	Glen Goff, Manager of Regulatory Affairs
Telephone: Telefax:	(505) 343-1131 Ext. 124 (505) 344-8112
Preparation Date:	05/21/02
Device Trade Name:	Cell Robotics Ultra-Light Laser System
Common Name:	Erbium:YAG laser device
Classification Name:	Instrument, Powered, Laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device:	Schwartz Electro-Optics TriLase2940, K# 954013 Cell Robotics Er:YAG Laser System, K# 970461 Asceplion-Meditec Dermastar Er:YAG Laser System, K#014057
Description of the Device	The Cell Robotics Ultra-Light Laser System is an Er:YAG laser producing emission at a wavelength of 2940nm. The laser consists of two interconnected sections: The cabinet which houses the power supply, the cooling system and the electronics, and; the umbilical cables and the handpiece, which houses the laser.
Intended Use of the Device	The Cell Robotics, Inc. Ultra-Light Laser System is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthamology.

Nonclinical Performance Data:	None Required
Clinical Performance Data:	None Required
Conclusion:	The Cell Robotics Ultra-Light Laser System is substantially equivalent to other existing legally marketed laser systems currently in commercial distribution.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Cell Robotics, Inc.
Glen Goff
Manager of Regulatory Affairs
2715 Broadbent Parkway, NE
Albuquerque, New Mexico 87107

Re: K021946
Trade/Device Name: Cell Robotics Ultra-Light Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 12, 2002
Received: June 13, 2002

Dear Mr. Goff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K021946

Device Name: Cell Robotics Ultra-Light Laser System

Indications for Use:

The Cell Robotics, Inc. Ultra-Light laser system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthamology.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021946

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)